NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Valve-in-valve TAVI for aortic bioprosthetic valve dysfunction

The aortic valve controls the flow of blood out of the left chamber of the heart (left ventricle) to the body's main artery (aorta). A faulty aortic valve can be replaced with an artificial valve through open heart surgery or by transcatheter aortic valve implantation (TAVI). If a bioprosthetic artificial valve (made of biological tissue) fails, another bioprosthetic valve can be placed inside it using a tube (catheter) inserted through a small cut in the skin and then through a large artery. This is known as valve-in-valve TAVI. The aim is to replace the faulty valve without the need for open heart surgery.

The National Institute for Health and Care Excellence (NICE) is looking at valve-in-valve TAVI for aortic bioprosthetic valve dysfunction. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 21 March 2019

Target date for publication of guidance: June 2019

1 Draft recommendations

1.1 Current evidence on the safety and efficacy of valve-in-valve TAVI (ViV-TAVI) for aortic bioprosthetic dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 Details of all patients should be entered into the UK TAVI registry.

1.3 Device-related adverse events should be reported to the Medicines and Healthcare products Regulatory Agency.

1.4 Patient selection should be done by a multidisciplinary team, which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging and,

when appropriate, a cardiac anaesthetist and a specialist in elderly medicine. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them.

1.5 During the consent process, patients should be told about all treatment options, and their advantages and disadvantages.

1.6 ViV-TAVI is a technically challenging procedure that should only be done in specialised centres, and only by clinicians and teams with special training and experience in complex endovascular interventions. Units doing this procedure should have both cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care.

2 The condition, current treatments and procedure

The condition

2.1 The 2 main indications for aortic valve replacement are aortic stenosis and aortic regurgitation. Symptoms of both conditions typically include shortness of breath and chest pain on exertion. The increased cardiac workload can lead to heart failure.

Current treatments

2.2 Aortic valve replacement with an artificial prosthesis (biological or mechanical) is the conventional treatment for patients with severe aortic valve dysfunction. Valves may be placed by either open heart surgery or using TAVI. Although bioprosthetic valves have some advantages over mechanical valves, they may degenerate and fail over time. The standard treatment for a failed bioprosthetic valve is open heart surgery, with a further valve replacement. Reoperative surgery is associated with significant morbidity and a higher risk of mortality than primary surgery.

2.3 Valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) has been developed as a less invasive alternative treatment that avoids the need for cardiopulmonary bypass. It can be used for treating failed bioprosthetic aortic valves originally placed either by open heart surgery or TAVI.

The procedure

2.4 The procedure is done with the patient under general or local anaesthesia with sedation, using fluoroscopy. Prophylactic antibiotics and anticoagulant medication are given before and during the procedure. Temporary peripheral extracorporeal circulatory support (usually through the femoral vessels) is very occasionally used.

2.5 A new prosthetic valve is mounted within a stent, which is either self-expanding or expanded using balloon inflation. It is delivered by a catheter across the failed bioprosthetic aortic valve. Access to the aortic valve can be achieved transluminally, with entry to the circulation through the femoral or other large artery (sometimes known as a percutaneous or endovascular approach), or through apical puncture of the left ventricle (a transapical or transventricular approach). In the transluminal approach, surgical exposure and closure of the artery may be needed. How access to the aortic valve is achieved depends on whether there are factors that make the passage of a catheter through the circulation difficult, such as peripheral arterial disease.

2.6 The procedure is technically similar to TAVI for aortic stenosis into a native aortic valve, but some modifications to the technique have been reported. The new prosthetic valve is placed tightly into the orifice of the failed bioprosthetic valve, pushing the old valve leaflets aside. Gradual valve deployment (without rapid inflation of the balloon) is done and angiography is used to ensure accurate positioning of the valve. The old prosthesis is also used as a guide for positioning the new valve. The external diameter of the new

valve should usually match or exceed the internal diameter of the old valve.

3 Committee considerations

The evidence

3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 3 systematic reviews and meta-analysis and 8 case series, and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: survival, hemodynamic improvement, symptom relief and improvement in quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: mortality, stroke, myocardial infarction and paravalvular leak.

3.4 Two commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

3.5 This guidance is a review of NICE's interventional procedures guidance on transcatheter valve-in-valve implantation for the treatment of aortic bioprosthetic valve dysfunction.

Committee comments

3.6 There is a move towards using sedation rather than general anaesthesia for this procedure.

3.7 The longer-term evidence on ViV-TAVI is from earlier-generation TAVI devices and the technology is evolving. Longer-term evidence

is needed and this should be taken into account by the multidisciplinary team.

3.8 The replacement valve used for ViV-TAVI can be smaller than the original, increasing the risk of aortic outflow obstruction.

3.9 There is a risk of patient−prosthesis mismatch.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
February 2019